EXHIBIT 8

AMERICAN ARBITRATION ASSOCIATION

NEW YORK, NEW YORK

ACORDA THERAPEUTICS, INC.,	)	
	)	
Claimant,	)	
	)	
v.	)	Case No. 01-20-0010-8421
	)	CONFIDENTIAL
ALKERMES PLC,	)	
	)	
Respondent.	)	
	)	

ALKERMES'S MEMORANDUM IN SUPPORT OF ITS MOTION IN LIMINE TO PRECLUDE ACORDA FROM INTRODUCING ANY EVIDENCE, TESTIMONY OR ARGUMENTS REGARDING DAMAGES RELATED TO SUPPLY PRICE

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INTRODUCTION

The Panel should issue a pre-hearing ruling precluding Acorda from introducing any evidence, testimony or argument that it is entitled to damages related to Acorda's Supply Price payments. The Panel should enter this order for two independent reasons. First, even if Acorda were to prevail under *Brulotte*, any remedy remaining following the summary judgment rulings would apply only to *royalties*, not to the separate Supply Price, because *Brulotte* has no impact on any payments other than royalties.[1] Second, while the Panel held that Acorda may have a remedy "pursuant to a theory of unjust enrichment/restitution for payments made *under protest* beginning in July 2020" (Order #23 at 13), Acorda has never made a Supply Price payment under protest; Acorda's protests were explicitly limited to the royalties paid pursuant to the License Agreement. For each independent reason, Acorda has no surviving claim to recover any portion of its Supply Price payments. The issue is clear, and the Panel should resolve it now to simplify the issues and allow the hearing to proceed in an efficient and economical manner.

I. Factual Background

A. The Elan Royalty and Supply Price are distinct and clearly defined by the separate respective agreements

In 2003, when Alkermes and Acorda revised their 1998 agreement relating to the use of dalfampridine to treat MS, they divided Acorda's payment obligations to Alkermes into two discrete components, embodied in two separate agreements—(1) the License Agreement; and (2) the Supply Agreement.

Under the 2003 License Agreement, Acorda pays a defined "Elan Royalty." Specifically, under Article 5.6 of the 2003 Amended and Restated License Agreement, Acorda pays a "***royalty***

[1] For the same reasons, Acorda is not entitled to an adjustment of the Supply Price prospectively, even assuming *arguendo* the existence of a *Brulotte* violation.

of ten per cent (10%) of the NSP of" AMPYRA® in "consideration of the rights and license granted to Acorda to the Elan Patent Rights while there is a Valid Claim thereunder, and in consideration of . . . the Elan Know-How thereafter." Ex. A, License Agreement at Art. 5.6.1 (emphasis added); *see also id.* at Art. 5.6.2 ("In countries where there are no Valid Claims covering the Product and if there is no Competition, Acorda shall pay to Elan the applicable Elan ***Royalty*** set forth in Article 5.6.1 for sales in such countries; provided [certain conditions are met]" (emphasis added)).[2] Under the separate 2003 Supply Agreement, Acorda pays Alkermes a separately defined "Supply Price" for finished pharmaceutical dosage forms of AMPYRA® that Alkermes manufactures and supplies to Acorda. Ex. B, Supply Agreement at Cl. 5, 9.3.1. Clause 9.3.1 of the Supply Agreement defines "the '**Supply Price**'" as "the price of the Product [AMPYRA®] manufactured by" Alkermes as "equivalent to eight per cent (8%) of the NSP . . . ."[3]

These separate agreements thus unambiguously set forth two distinct payment arrangements. Acorda pays a 10% royalty as defined in the License Agreement in consideration for its license to Alkermes's intellectual property, and separately pays an 8% supply price, as defined in the separate Supply Agreement, in consideration for Alkermes manufacturing and supplying it with AMPYRA®. The agreements are clear that the Supply Price is not a "royalty."

B. The separation of the Elan Royalty and Supply Price stems from Acorda's request during negotiations of the 2003 agreements

The current payment structure of the agreements separating the Elan Royalty and the Supply Price is no accident, but the result of a carefully negotiated compromise. The negotiations between Acorda and Alkermes in 2002-2003 sought to preserve the economics from prior agreements that the parties had entered relating to dalfampridine, including the April 21, 1998

[2] In addition to the running 10% royalty, Acorda also paid lump sum and milestone royalties to Alkermes for its license to the Elan Patent Rights (but not for the Elan Know-How). *See* Ex. A, License Agreement at Arts. 5.2 & 5.3.
[3] The supply price for launch stock and samples is separately defined. *See* Ex. B, Supply Agreement at Cls. 9.1 & 9.2.

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Joint Venture License and Supply agreement ("1998 Agreement"). Ex. C, ALKERMES_00000543. In the 1998 Agreement, which applied to the use of dalfampridine in connection with MS (the indication for which AMPYRA is approved), Article 5.3.1 established a single all-inclusive payment of 18% of the NSP. *Id.* at -578 (Art. 5.3.1.).[4]

In 2002, Alkermes and Acorda began to negotiate an updated arrangement. Ex. D, ACOR-ALK-ARB0428431; Ex. E, Nesbitt Tr. at 139:9–140:12.[5] Among other goals, the parties wanted to differentiate between royalty and supply price payments while preserving the economics of the original agreement as much as possible. *See* Ex. E, Nesbitt Tr. at 75:6-17, 80:19-81:2, 104:1-7; Ex. F, Nesbitt Dep. Ex. 5, ACOR-ALK-ARB0425915 at -919 (proposing that the new arrangement would "[b]reak out royalty for license from payment for supply" from the older agreement). In negotiating the economics of the agreement, Alkermes proposed to keep as much of the payments as possible in the form of a royalty; Alkermes therefore proposed a 19% royalty and a supply price of $.10 cost per tablet shifting to $.075 per tablet after 100 million tablets. *See id.* at -919; Ex. E, Nesbitt Tr. at 147:20-149:7. But Acorda stated that it wanted to keep the "pricing as is," with the supply price remaining a percentage of NSP, and Acorda proposed having the supply price be greater than the royalty. Ex. G, ACOR-ALK-ARB0425922 at -925 (proposing a 7% royalty and 11% "supply price" with a "25% supply price reduction after 100MM tablets"); Ex. E, Nesbitt Tr. at 83:10-16. The ultimate arrangement embodied in the two separate agreements—a 10% *royalty* and an 8% *supply price*—was the result of compromise between the two parties. Ex. E, Nesbitt Tr. at 147:20-149:7.

This negotiation history confirms what the 2003 agreements unambiguously provide: the

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[4] Product was defined as an "oral sustained release dosage form" of 4-aminopyridine "for the treatment of symptoms of MS and/or the treatment of MS . . . ." Ex. C, ALKERMES_00000543 at -548 ¶ 13, -553 ¶ 40.

[5] Alex Nesbitt, former Associate Director at Elan, negotiated the 2003 agreements on behalf of Alkermes (then Elan). Ex. E, Nesbitt Tr. at 27:20-25, 64:22-65:8, 139:9-140:12.

agreements set out distinct royalty payments and supply payments, and the Supply Price payments are not patent royalties.

C. Acorda has never protested its Supply Price payments

Although, as the Panel is aware, Acorda began making certain payments to Alkermes under protest starting in July 2020, none of those protests ever was directed at the Supply Price. In the lead-up to this dispute, Acorda sent Alkermes a written letter followed by purchase orders protesting *royalty payments* under the License Agreement on the basis of a purported *Brulotte* violation, and two additional letters before it filed its demand for arbitration. But in all those communications, Acorda never mentioned (let alone contested) the 8% Supply Price.

On April 22, 2020, Acorda sent Alkermes a letter asserting that the "10% ***royalty rate*** in the [License] agreement . . . is unenforceable" under *Brulotte v. Thys Co.*, 379 U.S. 29 (1964). Ex. H, Pops Dep. Ex. 6, ALKERMES_00000001 at -002 (emphasis added). That letter never references the Supply Price or its 8% payment. Acorda's subsequent July 8, 2020 AMPYRA® purchase order contained a footnote stating that "Acorda will be making payment on this order as per ***the royalty rate stated in the License Agreement***. Acorda, however, reserves its right to seek an accounting of any overpayment of ***royalties*** and repayment of such by Alkermes ***in accordance with Section 5.9.5 of the License Agreement***." Ex. I, ALKERMES_00004483 (emphases added). The footnote referred Alkermes to its "letter dated April 22, 2020." *Id.* Again, this protest says nothing about the Supply Price. Acorda's subsequent purchase orders have contained identical footnotes to the one in the July 2020 purchase order, with no mention of Supply Price payments.

Acorda sent two additional letters to Alkermes following efforts by the parties to resolve the dispute before the Demand was filed. On June 26, 2020, Acorda sent Alkermes a letter "regarding the ***royalty rate*** paid to Alkermes" and requesting a call between the parties "[i]n accordance with Section 10.3 of the ***license agreement***." Ex. J, Pops Ex. 9,

ALKERMES_00004423 (emphases added). Subsequently on July 10, 2020, Acorda again sent Alkermes a letter concerning "the disputes between [the] companies regarding the forward-going ***royalty rate*** and past overpayments by Acorda, ***in connection with the license agreement*** on Ampyra®" and informed Alkermes that it would be initiating an arbitration proceeding, which it did that same month on July 28. Ex. K, ALKERMES_00004428 (emphases added). Nowhere in these communications, either, did Acorda reference the Supply Price or the Supply Agreement.

D. Acorda cannot recharacterize the Supply Price as a patent royalty in the face of the clear terms of the agreements and its own experts' opinions to the contrary

In Acorda's arbitration demand, it sought for the first time—and in direct conflict with the controlling terms of the agreements themselves—to recharacterize the Supply Price as a purported "supply royalt[y]." *See, e.g.*, Demand at ¶¶ 39, 52 & Claim II. To the extent Acorda may try to rely on this type of word-play to argue that it may recover past Supply Price payments if the Panel were to find a *Brulotte* violation, or to suggest that its written protests to royalty payments under the License Agreement somehow also applied to Supply Price payments under the Supply Agreement, its arguments should be rejected now as a matter of law. The only possible claims for which Supply Price payments were relevant were dismissed by the Panel.

Acorda's *Brulotte* claim itself within the Demand only references a "royalty pursuant to Article 5.6 of the License Agreement" and not any Supply Price. Demand at ¶¶ 41-44. The royalty pursuant to Article 5.6 is never greater than 10% of AMPYRA®'s NSP, so it cannot include the additional 8% Supply Price payments required by Article 9 of the Supply Agreement. Further, as alleged in the Demand, Acorda's claims relating to "supply royalties" are based not on *Brulotte*, but on the idea that the contractually agreed upon supply price—which is even lower than what Acorda itself proposed in negotiations—is not a "fair market rate." *Id.* at ¶¶ 45-47, 52. That is an antitrust argument, which has been dismissed.

Acorda's own experts recognize that the Supply Price was only relevant to potential antitrust damages. Acorda's damages experts were careful to distinguish between the contractually separate Supply Price payments and Elan Royalty payments. Mr. Malackowski opined on what a "reasonable supply cost" would be "[i]n the event that the Arbitrators find that Alkermes's 8% supply rate is supra-competitive." Ex. L, Malackowski Rpt. at 7, 40. He further recognized that the 10% payment is for a royalty set forth in the License Agreement, *id.* at 22, 25-26; and that the 8% payment is for a "supply price" under the separate Supply Agreement. *Id.* at 27. Similarly, Dr. Teece recognized that the 8% Supply Price is for supply of product under the Supply Agreement, Ex. M, Teece Rpt. at ¶ 17, and that the 10% payment is for the Elan Royalty under the License Agreement, *id.* at ¶ 14. Dr. Teece specifically recognized "[t]he IP royalty is not compensation for production, which instead is provided for under the terms of the Supply Agreement." *Id.* at ¶ 75. Dr. Teece also opined that the 8% Supply Price was a product of "Alkermes's monopoly power in the supply market," and its "[m]onopoly extension" post expiration of the '938 Patent, an evocation of antitrust concepts. *Id.* at ¶¶ 80, 93.

In short, Acorda and its experts recognize the explicit distinction between the Supply Agreement containing a Supply Price, and License Agreement containing a royalty. Acorda should not be allowed to keep Supply Price damages in play by impermissibly rewriting the words of the Supply Agreement to contain a supposed supply "royalty" that does not exist for purposes of improperly shoe-horning the Supply Price into its *Brulotte* arguments or retroactively purporting to have paid the Supply Price under protest.

II. <u>There Is No Legal Basis for Acorda to Recover Supply Price Damages</u>

Given that Acorda's only remaining claims are premised on an alleged *Brulotte* violation, Acorda has no claim for which the Panel could properly order that Alkermes return to Acorda any

past Supply Price payments (even if they had been made purportedly under protest, which they irrefutably were not, *see supra* at 4-5). The *Brulotte* doctrine is grounded in *patent law* considerations and applies only to post-expiry *patent royalties*, which the Supply Price indisputably is not. The Supreme Court in *Kimble* further clarified that *Brulotte* erects no barrier to other types of post-patent-expiry payments, "so long as tied to a non-patent right" such as know-how. *Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 454 (2015). Since non-patent *royalties* are not rendered unenforceable by a *Brulotte* violation, it necessarily follows that *non-royalty* payments like a supply price paid for manufacturing likewise are not touched by *Brulotte*. *Accord Hearing Components, Inc. v. Shure, Inc.*, 2009 WL 815526, at *7 (E.D. Tex. Mar. 26, 2009) (noting "the Court in *Brulotte* was largely concerned with royalties paid to patentees after a patent has expired" and that the licensee had "not cited, and the court ha[d] not found, any case in which a post-expiration supply obligation was found to be patent misuse per se"). Alkermes's right to receive the Supply Price is "tied to a non-patent right"—it is the payment Alkermes receives for manufacturing and supplying the physical AMPYRA® product for Acorda. *Brulotte* simply does not touch such payments.

While parol evidence is unnecessary to establish that *Brulotte* has no impact on the Supply Price (and, indeed, resort to parol evidence would be impermissible given the unambiguous language of the agreements), the negotiation history discussed above further corroborates why the Supply Price cannot be considered a royalty. Acorda specifically *rejected* Alkermes's proposal that the Supply Price would be based on cost per tablet, and Alkermes's proposal that all of the 18% payment other than actual manufacturing costs would be deemed a royalty. Instead, Acorda insisted—and prevailed—in classifying the 8% component of compensation *not* as a royalty, but as a supply price paid in consideration *not* for a patent license, but for the manufacturing and

supply of physical product. *See supra* at 2-4. Acorda presumably had its own reasons in 2003 for insisting the Supply Price comprise more than simply the actual manufacturing cost. Acorda cannot now rewrite the plain language of the agreements, and insist that the Supply Price somehow had been a royalty in disguise all along (particularly when Acorda rejected that very classification during contract negotiations) to suit its purposes in this arbitration. *Cf. Skymall, Inc. v. Zuckerman*, 2005 WL 2779604, at *3 (S.D.N.Y. Oct. 25, 2005) (discussing that contractual language with plain meaning "is not ambiguous merely because [a] part[y] urge[s a] different interpretation[] in the litigation" and that a "court should not find language ambiguous 'on the basis of the interpretation urged by one party, where that interpretation would strain the contract language beyond its reasonable and ordinary meaning.'" (citation omitted)).

The *Kimble* Court wrote that *Brulotte* "is simplicity itself to apply. A court need only ask whether a licensing agreement provides *royalties* for *post-expiration use of a patent*. If not, no problem." 576 U.S. at 459 (emphases added). Because the ***Supply Agreement*** and ***Supply Price*** indisputably do not involve *royalties* (let alone patent royalties) of any type, Alkermes's conduct in continuing to charge the Supply Price necessarily presents "no problem" in this case, regardless of how the Panel rules on the *Brulotte* issues with respect to royalties. There is no avenue, therefore, for Acorda to recover prior Supply Price payments, period.

III. Acorda Cannot Recover Supply Price Payments for the Additional Reason That Acorda Has Never Protested Them

Evidence concerning Supply Price payments should be excluded for a second, independently sufficient reason. In its summary judgment decision, the Tribunal has "conclude[d] that Acorda is not entitled to any refund where it failed to make any protest." Order #23 at 13. The indisputable evidence shows that Acorda never made a written protest to payment of the Supply Price, so Acorda has no claim for a refund of Supply Price payments.

As set out above, Acorda's protests to certain payments applied only to the royalties, not to the Supply Price. Acorda CEO Ron Cohen's April 22, 2020 letter to Alkermes CEO Richard Pops, in which Acorda first raised its *Brulotte* argument, asserted only that the "10% royalty rate" in the License Agreement is unenforceable; it is silent about the Supply Price. *Supra* at 4. Similarly, when Acorda first made a written protest around the time of payment in its July 8, 2020 purchase order, Acorda only made reference to the License Agreement, and indeed referenced the April 22 letter, which is only about the 10% royalty under the License Agreement; again, there was no reference to the Supply Agreement or the Supply Price. *Supra* at 4. None of Acorda's subsequent protests applied to the Supply Price, either—which makes sense, because the protest was based solely on *Brulotte*, and *Brulotte* has no effect on a contractual payment for the supply of product.

Given that Acorda did not make Supply Price payments under protest, it has no remedy to recover them now under the Panel's prior holdings and established law. *See* Order #23 at 11-14; *see also, e.g.*, *Overbay, LLC v. Berkman, Henoch, Peterson, Peddy & Fenchel, P.C.*, 128 N.Y.S.3d 56, 58 (App. Div. 2020) (citing *Neuner v Newburgh City School Dist.*, 459 N.Y.S.2d 874, 875 (App. Div. 1983) and explaining that a protest must be "in writing and made at the time of payment"). Because Acorda has no viable claim to recover any Supply Price payments, evidence about those payments would serve no purpose and be entirely irrelevant.

IV. A Pre-Hearing Ruling on This Issue is Appropriate

A pre-hearing ruling precluding Acorda from introducing evidence, testimony and argument regarding alleged Supply Price-related damages will facilitate an "efficient and economical" hearing by "simplifying the issues, and eliminating [a] frivolous claim[]," consistent with the governing rules. *See* AAA R-23, R-32; *see also* Fed. R. Civ. P. 16 (c)(2)(A). A pre-

hearing ruling on this issue is also appropriate because motions *in limine* are proper devices "designed to narrow the issues to be presented" at trial. *Lovejoy-Wilson v. Noco Motor Fuels, Inc.*, 242 F. Supp. 2d 236, 244 (W.D.N.Y. 2003). In particular, motions *in limine* may be useful vehicles for eliminating unnecessary time and energy spent at trial on damages unrecoverable as a matter of law.[6] Resolution of this issue involves a straightforward application of the agreement and *Brulotte*, and therefore is appropriately considered in the motion *in limine* context.

CONCLUSION

Alkermes respectfully requests that the Panel grant its motion precluding Acorda from presenting evidence, testimony or argument that it is entitled to Supply Price damages.

[6] *See, e.g.*, *Lovejoy*, 242 F. Supp. 2d at 244 (citing cases); *Summit Props. Int'l, LLC v. Ladies Pro. Golf Ass'n*, 2010 WL 4983179, at *2-5 (S.D.N.Y. Dec. 6, 2010) (holding that a party was not entitled to restitution damages as a matter of law and was therefore precluded from offering evidence relating to a restitution theory or damages); *EMI Music Mktg. v. Avatar Records, Inc.*, 334 F. Supp. 2d 442, 444 (S.D.N.Y. 2004) (granting motion *in limine* precluding party from presenting evidence related to punitive damages where such damages were unavailable as a matter of law); *Baxter Diagnostics, Inc. v. Novatek Med., Inc.*, 1998 WL 665138, at *1-3 (S.D.N.Y. Sept. 25, 1998) (similar); *see also In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 517 F. Supp. 2d 662, 666-67 (S.D.N.Y. 2007) (where motion focuses on *remedy* or relief sought rather than claims, it is properly considered as a motion *in limine* and not a summary judgment motion).

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